4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA-2016-D-4120]

Fruit Juice and Vegetable Juice as Color Additives in Food; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled "Fruit Juice and Vegetable Juice as Color Additives in Food." The draft guidance, when finalized, will help manufacturers determine whether a color additive derived from a plant material meets the specifications under certain FDA color additive regulations.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that we consider your comment on the draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on http://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-D-4120 for the draft guidance for industry entitled "Fruit Juice and Vegetable Juice as Color Additives in Food." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on http://www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Office of Food Additive Safety, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: With regard to the draft guidance: Laura A. Dye, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1275. With regard to the proposed collection of information: Ila Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North (3WFN), 10A63, 11601 Landsdown St., North Bethesda, MD 20852.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled "Fruit Juice and Vegetable Juice as Color Additives in Food." We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

When a food substance, including plant material, is deliberately used as a color, it is a color additive (see 21 CFR 70.3(f)). We have a statutory obligation to ensure that authorized (or listed) color additives are suitable and safe for their intended use. FDA has authorized the use of the color additive "fruit juice," under § 73.250 (21 CFR 73.250), that is prepared either by expressing the juice from mature varieties of fresh, edible fruits, or by the water infusion of the dried fruit. Similarly, § 73.260 establishes that the color additive "vegetable juice" is prepared either by expressing the juice from mature varieties of fresh, edible vegetables or by the water infusion of the dried vegetable. The underlying premise of §§ 73.250 and 73.260 is that the safety of fruit juice and vegetable juice as color additives for use in food is assured by the fact that the fruit or vegetable from which the color additive is derived has been safely consumed as food, such that there would not be safety concerns in using the juice or water soluble color components from the fruit or vegetable as a color additive. The fact that plant material can be eaten does not necessarily mean that juice from such plant material meets the specifications of these regulations. We also note that, in addition to the color additive regulations for fruit juice in § 73.250 and vegetable juice in § 73.260, we have authorized color additives derived from plant materials in separate color additive regulations, including § 73.169 (grape skin extract) and § 73.500 (saffron).

The draft guidance, when finalized, is intended to help manufacturers determine whether a color additive derived from a plant material meets the specifications for fruit juice under § 73.250 or vegetable juice under § 73.260. The draft guidance, including our interpretation of the terms used in §§ 73.250 and 73.260, is limited to these color additive regulations. The draft guidance does not address the use of fruit- or vegetable-derived color additives that are

authorized under different color additive regulations or that are the subject of a color additive petition.

Since we issued the color additive regulations for fruit juice and vegetable juice, we have received inquiries from industry regarding whether certain plant materials are covered by these color additive regulations. The draft guidance provides the criteria that should be used to determine if a plant material is a mature, fresh, edible fruit or a mature, fresh, edible vegetable under §§ 73.250 and 73.260. The draft guidance also encourages firms to consult us if they are unsure of the regulatory status of a substance that they propose to derive from plant materials for use as a color additive for food. Separately, we have posted on our Web site a summary table of the informal opinions that we have issued in response to the specific inquiries we have received regarding the applicability of §§ 73.250 and 73.260. The draft guidance document contains the Web site link to the summary table.

II. Paperwork Reduction Act of 1995

The draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520). The collections of information in 21 CFR 71.1 have been approved under OMB control number 0910-0016.

The draft guidance also refers to new collections of information found in FDA regulations. Under the PRA, Federal Agencies must obtain approval from OMB for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party.

Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information before submitting the information to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed new collection of information set forth in this document.

With respect to the following collection of information, we invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Fruit Juice and Vegetable Juice as Color Additives in Food; Draft Guidance for Industry--OMB Control Number 0910-NEW

The draft guidance, when finalized, will help manufacturers determine whether a color additive derived from a plant material meets the specifications for fruit juice under § 73.250 or vegetable juice under § 73.260. Information in the draft guidance regarding submission of a color additive petition has been previously approved by OMB in accordance with the PRA under OMB control number 0910-0016.

The proposed new information collection provides manufacturers the opportunity to request a meeting with FDA if they are unsure whether a color additive that is derived from plant material and that is intended for use in food meets the identity for fruit juice or vegetable juice in

§ 73.250 or § 73.260. When manufacturers request a meeting, the draft guidance suggests that they provide the scientific name, common name(s), origin, cultivation state, and life-stage of the plant material from which they wish to derive the color additive, and which plant structure will be declared the mature, fresh, edible fruit or vegetable, as well as a complete description of the manufacturing process for the color additive. Manufacturers also may provide information to us to verify that the plant material can be consumed for its taste, aroma, or nutrient properties in its fresh state and to document the amount and frequency of consumption and the history of safe consumption. If we determine that a proposed color additive does not meet the specifications for fruit juice or vegetable juice under § 73.250 or § 73.260, the manufacturer may submit a color additive petition, the collection of information for which has been approved under OMB control number 0910-0016.

Description of respondents: The respondents to this collection of information are manufacturers who are trying to determine whether a color additive derived from a plant material meets the specifications for fruit juice under § 73.250 or vegetable juice under § 73.260.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Color manufacturer's request for meeting and identification of fruit juice or vegetable juice information	5	1	5	1	5
Manufacturer's collection of data supporting the plant material as a consumable food, amount and frequency of consumption, and history of safe consumption by humans	5	1	5	24	120
Total					125

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA's estimate of the number of respondents and number of responses in table 1 is based on the average number of meetings that are expected to be requested annually by manufacturers over the next 3 years. Based on past experience, we expect the request for a meeting and the submission of fruit juice or vegetable juice information can be completed by a qualified plant taxonomist in less than 1 hour. We also expect that some manufacturers may want to provide research supporting the plant material as a consumable food, the amount and frequency of consumption, and the history of safe consumption of the mature fruit or vegetable by humans. We estimate that, in these cases, it would take a qualified toxicologist up to 3 days (24 working hours) to perform a thorough literature and plant database search. This estimate includes the time we expect it would take for a submitter to compile the information for submission to FDA.

To be conservative, the total number of annual burden hours, therefore, would be 125 hours, which would include 5 hours to complete the initial request for a meeting and of the submission of associated information to FDA, and 120 hours to complete a literature and database search and to present this information for submission to FDA.

Before the proposed information collection provisions contained in the draft guidance become effective, we will publish a notice in the Federal Register announcing OMB's decision to approve, modify, or disapprove the information collection provisions. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either http://www.fda.gov/FoodGuidances or http://www.regulations.gov. Use the FDA Web site listed in the previous sentence to find the most current version of the draft guidance.

Dated: December 8, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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